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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,363	03/21/2002	Hiroko Matsunaga	NITT.0049	5840
38327	7590	02/10/2005	EXAMINER	
REED SMITH LLP			KIM, YOUNG J	
3110 FAIRVIEW PARK DRIVE, SUITE 1400			ART UNIT	
FALLS CHURCH, VA 22042			PAPER NUMBER	

1637

DATE MAILED: 02/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/009,363

Applicant(s)

MATSUNAGA ET AL.

Examiner

Young J. Kim

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above claim(s) 13-31 and 35-43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 and 32-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 March 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>12/10/01 & 10/3/02</u> . | 6) <input checked="" type="checkbox"/> Other: <u>See Continuation Sheet</u> . |

Continuation of Attachment(s) 6). Other: Translation of JPA No. 10-257887.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I, claims 1-12 and 31-34 in the reply filed on October 25, 2004 is acknowledged.

It is noted that the Restriction mailed out on October 8, 2004, contained a typographical error. In that restriction, claim 35 was inadvertently omitted in the groupings of the claims. However, it should be apparent that claim 35 should have been included in Group II. In consistent with Applicants' election, claim 35 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions.

In sum, claims 13-30 and 35-43 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on October 25, 2004.

Information Disclosure Statement

The IDS received on December 10, 2001 and October 3, 2002 are acknowledged.

The signed copies of their PTO-1449 are attached hereto.

With regard to reference WO 96/07916 on the IDS received on October 3, 2002, this reference does appear to be material to the invention of the instant application. It appears that the document should have been WO 96/07917.

While the '07916 patent is considered, should Applicants desire that the '07917 patent be considered, Applicants are advised to submit a supplemental IDS listing the patent document on the record.

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All Japanese documents cited in IDS received on December 10, 2001 and October 3, 2002 have been considered to the extent of their English-translated Abstracts.

Drawings

The drawings filed on March 21, 2002 are acceptable.

Specification

The abstract of the disclosure is objected to for having in excess of 150 words (MPEP 608.01(b)). Correction is required. See MPEP § 608.01(b).

Claim Interpretation

Applicants are reminded that the intended uses recited in the instant claims are not given patentable weight so long as the product of the prior art teaches all of the elements claimed by the instant product claims.

See MPEP 2106(II)(C):

“Language that suggests or makes optional but does not require steps to be performed or does not limit a claim to a particular structure does not limit the scope of a claim or claim limitation. The following are examples of language that may raise a question as to the limiting effect of the language in a claim:

(A) statements of intended use or field of use...”

Claim Rejections - 35 USC § 112

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 12 recites the phrase, "the external form of which has a circular or square section perpendicular to the axis of rotational symmetry *thereof*." It is unclear what metes and bounds are embraced by the term, "thereof."

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 6, and 31 are rejected under 35 U.S.C. 102(a) as being anticipated by Kuhara et al. (Japanese Patent Publication 10-257887, published September 29, 1998, IDS reference).

For the purpose of art rejection, the claimed product is interpreted as having the following elements:

a) a sample preparation instrument comprising one or a plurality of sample preparation units, each sample preparation unit comprising:

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- i) an upper opening;
 - ii) a lower opening;
 - iii) a channel connecting the upper and the lower openings, said channel comprising a first filter, a second filter, and a third filter;
- b) a holding member for holding the sample preparation unit or units;
- c) a means for controlling the temperature of a PCR reaction;
- d) an irradiation means; and
- e) a detection means.

It should be noted that the English translation of the Kuhara et al. reference has been provided through: <http://www19.ipdl.ncipi.go.jp/PA1/cgi-bin/PA1INIT?1107467737000>, which provides machine translation of published Japanese applications.

Kuhara et al. disclose an apparatus that is capable of analyzing many genes at a time by a plural number of reaction vessels. The gene analyzer comprises an upper and a lower opening, connected by a channel comprising: a) waterproof membrane 1 as a lowermost layer; b) porous membrane 2 comprising at least two or more of a porous membrane upper layer 2a and a porous membrane lower layer 2b, differing in material, wherein said material is disclosed as functioning as a filter membrane (Solution section in the provided translation of the publication).

The membranes are disclosed as permeating genes and proteins without permeating cells (Solution section).

The apparatus is disclosed as capable of analyzing many genes at a time by performing amplification, purification, immobilization of genes and hybridization in the same reaction sites.

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The artisans disclose that after the target genes are hybridized with markers, either radioactive or fluorescent, the results are detected, which would necessarily require that a detection module as well as the irradiation element be present in the apparatus [0021, Detailed Description].

Therefore, the apparatus of Kuhara et al. anticipate instant claims 1, 6, and 31.

Claims 6 and 9-12 rejected under 35 U.S.C. 102(e) as being anticipated by Colpan (U.S. Patent No. 6,277,648, issued August 21, 2001, filed June 2, 1994).

Colpan discloses a filter unit which comprises: a) an upper and a lower opening (element 50 and 60, Figure 1); b) channel connecting these openings (element 40, Figure 1); c) a first, a second, and a third filter (elements 20, 21, and 22, Figure 1), thereby anticipating claim 6.

The second filter and the third filter of Colpan are disclosed as being in contact with each other (Figure 1), anticipating claim 8.

The unit encasing the filters is known in the art to be made of plastic, anticipating claim 10.

The filter unit of disclosed as being in cylindrical format (column 2, line 43), which would necessarily have an axis of rotational symmetry, anticipating claims 11 and 12.

Therefore, Colpan anticipates the invention as claimed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2-12 and 32-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuhara et al. (Japanese Patent Publication 10-257887, published September 29, 1998, IDS reference).

For the purpose of art rejection, the claimed product is interpreted as having the following elements:

- a) a sample preparation instrument comprising one or a plurality of sample preparation units, each sample preparation unit comprising:
 - i) an upper opening;
 - ii) a lower opening;
 - iii) a channel connecting the upper and the lower openings, said channel comprising a first filter, a second filter, and a third filter;
- b) a holding member for holding the sample preparation unit or units;
- c) a means for controlling the temperature of a PCR reaction;
- d) an irradiation means; and
- e) a detection means.

Kuhara et al. disclose an apparatus that is capable of analyzing many genes at a time by a plural number of reaction vessels. The gene analyzer comprises an upper and a lower opening, connected by a channel comprising: a) waterproof membrane 1 as a lowermost layer; b) porous membrane 2 comprising at least two or more of a porous membrane upper layer 2a and a porous

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membrane lower layer 2b, differing in material, wherein said material is disclosed as functioning as a filter membrane (Solution section in the provided translation of the publication).

The membranes are disclosed as permeating genes and proteins without permeating cells (Solution section).

The apparatus is disclosed as capable of analyzing many genes at a time by performing amplification, purification, immobilization of genes and hybridization in the same reaction sites.

The artisans disclose that after the target genes are hybridized with markers, either radioactive or fluorescent, the results are detected, which would necessarily require that a detection module as well as the irradiation element be present in the apparatus [0021, Detailed Description].

Kuhara et al. do not disclose the actual location of the irradiations means with respect to the sample preparation units, nor do the artisans explicitly state the size of the filters with respect to each other.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Kuhara et al. to arrive at the claimed invention for the following reasons.

The need in the art expressed by Kuhara et al. and the instant applicants are identical in that the artisans express a need in the art for a system which conducts extraction of nucleic acids from a sample, PCR and detection, fully automatically:

“Currently there is no system existing for carrying out the steps of extraction of DNA or RNA from a sample, PCR and detection fully automatically.” (page 4, lines 20-23, instant specification).

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“The technical problem of this invention is by performing magnification and purification of a gene, fixed actuation to porous membrane, and hybridization all over a reaction-of-identity place to offer the gene-analysis equipment and the approach of processing many samples at once.” (Kuhara et al., *Detailed Description*, [0006]).

Kuhara et al. employ an apparatus which employ three filter system arranged in succession for the purpose of extraction, purification, amplification, followed by their detection, all in the same apparatus.

While Kuhara et al. do not explicitly teach that the reaction vessels be arranged in a straight line, the irradiation means be parallel or perpendicular to the reaction vessels, the art of fluorescent detection has been well-established in the art of hybridization, and certainly, one of ordinary skill in the art, at the time the invention was made would have had a reasonable expectation of success at modifying the location of the irradiation module for such modification is routine and the best position is determined via empirical means.

With regard to the filter size, barring evidence to the contrary and secondary characteristics, such is deemed to be design preference.

MPEP 2144.04 (I) states:

“In re Seid , 161 F.2d 229, 73 USPQ 431 (CCPA 1947) (Claim was directed to an advertising display device comprising a bottle and a hollow member in the shape of a human figure from the waist up which was adapted to fit over and cover the neck of the bottle, wherein the hollow member and the bottle together give the impression of a human body. Appellant argued that certain limitations in the upper part of the body, including the arrangement of the arms, were not taught by the prior art. The court found that matters relating to ornamentation only which have no mechanical function cannot be relied upon to patentably distinguish the claimed invention from the prior art.).

Alternatively, MPEP 2144.02 (IV)(A) and (B) states:

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"A. Changes in Size/Proportion

In re Rose , 220 F.2d 459, 105 USPQ 237 (CCPA 1955) (Claims directed to a lumber package "of appreciable size and weight requiring handling by a lift truck" where held unpatentable over prior art lumber packages which could be lifted by hand because limitations relating to the size of the package were not sufficient to patentably distinguish over the prior art.); In re Rinehart, 531 F.2d 1048, 189 USPQ 143 (CCPA 1976) ("mere scaling up of a prior art process capable of being scaled up, if such were the case, would not establish patentability in a claim to an old process so scaled." 531 F.2d at 1053, 189 USPQ at 148.).

In Gardner v. TEC Systems, Inc., 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984), the Federal Circuit held that, where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and *a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device.*

B. Changes in Shape

In re Dailey, 357 F.2d 669, 149 USPQ 47 (CCPA 1966) (The court held that the *configuration* of the claimed disposable plastic nursing container *was a matter of choice which a person of ordinary skill in the art would have found obvious* absent persuasive evidence that the particular configuration of the claimed container was significant.)."

Whether the second filter has an area smaller than the area of the first filter, the apparatus has a plurality of preparation units arranged in a straight line, or said units have an axis of rotational symmetry, such are modifications which do not patentably distinguish the claimed product over the product of Kuhara et al. and obvious to one of ordinary skill in the art as discussed above.

Therefore, the invention as claimed is *prima facie* obvious over the cited reference.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Colpan (U.S. Patent No. 6,277,648, issued August 21, 2001, filed June 2, 1994) as evidenced by Shirasaki et al. (Japanese Patent Application publication No. 04-207195, published July 29, 1992, IDS reference).

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Colpan discloses a filter unit which comprises: a) an upper and a lower opening (element 50 and 60, Figure 1); b) channel connecting these openings (element 40, Figure 1); c) a first, a second, and a third filter (elements 20, 21, and 22, Figure 1).

Colpan does not explicitly disclose that the second filter comprise a smaller area than the area of the first filter.

Shirasaki et al. disclose a filter unit comprising filters wherein the second filter is smaller in area than the first filter (Figure 1).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Colpan to arrive at the claimed invention for the following reasons.

While Colpan does not explicitly teach that the second filter have a smaller area than the first filter, barring evidence to the contrary and secondary characteristics, such is deemed to be design preference.

MPEP 2144.04 (I) states:

“In re Seid , 161 F.2d 229, 73 USPQ 431 (CCPA 1947) (Claim was directed to an advertising display device comprising a bottle and a hollow member in the shape of a human figure from the waist up which was adapted to fit over and cover the neck of the bottle, wherein the hollow member and the bottle together give the impression of a human body. Appellant argued that certain limitations in the upper part of the body, including the arrangement of the arms, were not taught by the prior art. The court found that **matters relating to ornamentation only which have no mechanical function cannot be relied upon** to patentably distinguish the claimed invention from the prior art.).

Alternatively, MPEP 2144.02 (IV)(A) and (B) states:

“A. Changes in Size/Proportion

In re Rose , 220 F.2d 459, 105 USPQ 237 (CCPA 1955) (Claims directed to a lumber package "of appreciable size and weight requiring handling by a lift truck" where held unpatentable over prior art lumber packages which could be lifted by hand because

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limitations relating to the size of the package were not sufficient to patentably distinguish over the prior art.); In re Rinehart, 531 F.2d 1048, 189 USPQ 143 (CCPA 1976) ("mere scaling up of a prior art process capable of being scaled up, if such were the case, would not establish patentability in a claim to an old process so scaled." 531 F.2d at 1053, 189 USPQ at 148.).

In Gardner v. TEC Systems, Inc., 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984), the Federal Circuit held that, where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and *a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device.*

B. Changes in Shape

In re Dailey, 357 F.2d 669, 149 USPQ 47 (CCPA 1966) (The court held that the *configuration* of the claimed disposable plastic nursing container *was a matter of choice which a person of ordinary skill in the art would have found obvious* absent persuasive evidence that the particular configuration of the claimed container was significant.)."

Whether the second filter has an area smaller than the area of the first filter or not, such modification does not patentably distinguish the claimed product over the product of Colpan and obvious to one of ordinary skill in the art as discussed above.

Therefore, the invention as claimed is *prima facie* obvious over the cited references.

Conclusion

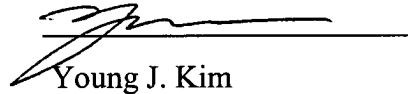
No claims are allowed.

Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (571) 272-0785. The Examiner can normally be reached from 8:30 a.m. to 6:00 p.m. Monday through Thursday. If attempts to reach the Examiner by telephone are unsuccessful, the Primary Examiner in charge of the prosecution, Dr. Kenneth Horlick, can be reached at (571) 272-0784. If the attempts to reach the above Examiners are unsuccessful, the Examiner's supervisor, Gary Benzion, can be reached at (571) 272-0782. Papers related to this application may be submitted to Art Unit 1637 by facsimile transmission. The faxing of such papers must conform with the notice published in

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the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. All official documents must be sent to the Official Tech Center Fax number: (571) 273-8300. For Unofficial documents, faxes can be sent directly to the Examiner at (571) 273-0785. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.



Young J. Kim
Patent Examiner
Art Unit 1637
2/3/05

YOUNG J. KIM
PATENT EXAMINER

yjk